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Patients' Understanding of Information Provided During Consent Process for Fixed Prosthodontic Treatment: A Mixed Methods Study at Dental Facilities in Kampala

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ABSTRACT

Introduction

Obtaining valid informed consent requires that patients understand treatment information. This is crucial for irreversible procedures, like fixed prosthodontic treatment, where dentists are required to communicate highly technical information to patients with different literacy levels and treatment expectations. Failure of patients to understand some aspects of the treatment may result in dissatisfaction and complaints. There is limited data about dental patients' understanding of treatment information in Uganda.

Aim and objectives: This study explored patients' understanding of information provided for fixed prosthodontic treatment at two dental care facilities in Kampala, Uganda.

Design

Parallel-convergent mixed methods

Methods

A survey was carried out on 216 patients and 19 in-depth interviews at two dental facilities. The patients had received information from their dentists about the fixed prosthodontic treatment they were to undergo. Quantitative data were collected using a pretested semi-structured interviewer-administered questionnaire. The questionnaire consisted of 5 items on a 4-point Likert scale and a checklist of 19 items to collect data on patients' subjective and objective understanding of the information provided, respectively. An interview guide facilitated the interviews. Quantitative data were analysed using descriptive statistics and Chi-square statistics. Total scores were computed for the assessment of objective understanding and categorized as adequate, moderate, or inadequate understanding, on attaining 80-100%, 50-79% or less than 50% of the maximum possible score. Qualitative data were analysed using thematic analysis.

Results

Over three quarters (> 85.0%) of the patients reported to have received the information during a verbal discussion with their dentist at prior appointment. Several participants reported that they were not informed about the possible risks (48.4%) or alternative treatments (22.2%). More than two-thirds felt that they had understood well (subjective understanding) many aspects of the treatment information, but only 13.4% of them had an adequate objective understanding. Treatment procedures and alternative treatment options were the most difficult to understand. There was no significant association between subjective and objective understanding.

Conclusions

Most participants did not adequately understand the information. Results indicate the need to develop interventions to enhance patient understanding of information provided during the consent process and measures for objective assessment of' understanding.

Keywords

fixed prosthodontic treatment, informed consent, information, understanding.

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INTRODUCTION

Informed consent obtained from patients undergoing clinical procedures is important not only for ethical and legal reasons but also for the quality of care.[1] Key to the success of the

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consent process is the ability of a patient to understand the information provided and be able to make autonomous and informed decisions.[2-5] This is particularly important for irreversible procedures such as fixed prosthodontics. In addition, patients often have high or unrealistic expectations of the outcomes, and failure to understand the treatment as well as the limitations may result in dissatisfaction.[2] This could trigger legal action.[2] Patient understanding of treatment information allows cooperation, improves trust, strengthens the dentist-patient relationship, satisfaction, and reduces the likelihood of misconceptions concerning treatment, and litigations.[2, 6]

The importance of ensuring that patients understand the information provided has been emphasized in various ethical codes.[7, 8] For instance, in Uganda, Article 10 of the Patient's Charter states that "information shall be communicated to the patient at the earliest possible stage in a manner that he/she is expected to understand in order to make a free informed, and independent choice".[9] This Charter serves as a key guideline in Uganda's healthcare system, emphasizing patient rights and the responsibility of healthcare providers to ensure effective communication.

While it is critical for patients to understand the information provided during the informed consent process, available literature from medical specialties reports several shortcomings in practice, including difficulties in patient recall, poor understanding or knowledge, and misconceptions of treatment information.[5,10-12] However, there is limited data on patients' understanding of the information provided during consent for dental care, and the scenario is the same in Uganda. This is particularly of concern for complex procedures such as fixed prosthodontic treatment (FPT), in which dentists must communicate highly technical and specialised information to patients with varying literacy levels and socio-cultural backgrounds.[2] There is also a need for an objective assessment of dental patients' understanding of treatment information before consent.

Therefore, this study aimed to explore patients' understanding of the information provided during the informed consent process for FPT among patients attending two dental care facilities within Kampala. It was hypothesized that, despite patients receiving information, they did not adequately understand the treatment information provided during the consent process.

MATERIAL AND METHODS

Study design and approach

The study employed a parallel, convergent mixed-methods design that included a survey and in-depth interviews. Both quantitative and qualitative methods were used to gain in-depth knowledge of how well patients understood the information provided during the consent process. The qualitative approaches clarified areas of inadequate understanding in the collected interviews and enabled understanding of the complex issues related to the communication of information, and patient's understanding. The study was approved by the Makerere University School of Medicine Research Ethics Committee (Mak-SOMREC-2022-418) and the Uganda National Council of Science and Technology (HS2914ES). Written informed consent was obtained from all participants before enrolment. The ethical considerations followed the guidelines of the Declaration of Helsinki.

Study setting

This study was conducted at two dental care facilities in Kampala, Uganda, between September 2023 and March 2024. The two hospitals were the Mulago and Makerere University Dental Hospitals (MUK-DH). Mulago is a national referral hospital (MNRH) that registers approximately 30 patients for fixed prosthodontics monthly. MUK-DH is a teaching and oral health service delivery facility for Makerere University that registers approximately 40 patients for fixed prosthodontic treatment monthly

Study population, sample size determination, and sampling procedure

The study was conducted among patients aged ≥ 18 years who had treatment plans involving FPT, had received information concerning their treatment from their dentists, and agreed to participate. Patients with a background in dental education, those on treatment for mental health issues, or those unable to speak English or Luganda were excluded.

The sample size was calculated using a statistical formula with a finite population correction:[13] $n = \frac{n_0 N}{n_0 + (N-1)}$, where n = sample size; no = (Z2PQ)/d2; N is population size; Z is 1.96, P is the proportion (considering an arbitrary value of 50% as no previous study in Africa); $Q = 1 - P$, d = 5%. Given that approximately 420 (N) patients sought FPT at the two hospitals over six months, the estimated sample size was 200, which was increased by 10% to 220 to account for missing data.

Proportional allocation was used to ensure adequate representation of each facility. Consecutive sampling was used to select participants at the dental facilities. For qualitative data, nineteen participants were purposively selected based on data saturation.

Data collection and quality control

Four research assistants (dentists) collected quantitative data using an interviewer-administered questionnaire (Supplementary file 1) in either English or Luganda. The questionnaire comprised three parts. Part I solicited socio-demographic information and service-related factors. Part II comprised five items on the subjective understanding of the information on a four-point Likert scale assessing patients' understanding of dental problems, proposed treatment procedures, benefits, probable risks, and alternative treatments. The Likert scale had the following alternatives: (1) "patient did not understand the item at all," (2) "somewhat understood," (3) "understood well," and (4) "understood very well." If participants believed they were not informed about a certain item, they were prompted to select not informed = 0. Part III contained a checklist of 19 items for the assessment of objective understanding of the information, including 5 items for the procedure, 6 regarded benefits, 6 probable risks, and 2 items concerning alternative treatments. The responses were "Disagree" (1), "Unsure/ I do not know" (2), and "Agree" (3). The questionnaire was developed based on the validated Quality of Informed Consent Tool for assessment of both subjective and objective understanding in research settings.[14] The checklist was developed based on literature regarding consent information for FPT and was reviewed by 3 dentists. The questionnaire was piloted among 15 patients to assess its clarity and reliability, achieving a Cronbach's alpha of 0.776. Data from the pilot study were included in the main survey.

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In-depth interviews (IDIs) were conducted by the principal investigator and a trained research assistant among 19 patients. The IDIs were conducted in either English or Luganda, using an interview guide (Supplementary file 2), and lasted 15-25 minutes. The interview guide included items to explore patients' views about: the information provided and their understanding of the information provided, decision-making, and suggestions to improve patients' understanding. The interviews were audio-recorded and supplemented with notes.

The study teams were trained before data collection, and daily checks were conducted to ensure the accuracy and completeness of the data. The trustworthiness of qualitative findings was demonstrated through the concepts of credibility, transferability, dependability, and confirmability. Credibility was enhanced through data triangulation, while the dependability of findings is illustrated through the well-documented methods. Study findings are derived from the data.

Data analysis

Quantitative data were analysed using STATA version 14.0 and summarized using descriptive statistics. Responses for the assessment of objective understanding were recorded as follows: correct=2, unsure/I do not know=1, and incorrect=0. Total scores were computed for each domain and categorized as: "adequate understanding" if 80-100% of the maximum possible score was attained, "moderate understanding" for 50-79%, and "inadequate understanding" for less than 50%. This categorization of scores was adapted from a systematic review of the comprehension of informed consent for surgery and clinical research.[15] Chi-square ($\chi 2$) statistic was used to determine the relationship between patients' subjective and objective understanding. Statistical significance was set at $P < 0.05$.

For qualitative data, audio recordings were transcribed verbatim. Three transcripts were translated from Luganda into English and verified for their accuracy. Thematic analysis was conducted using both inductive and deductive approaches using NVivo version 12. The PI and a social scientist with expertise in qualitative methods analysed the data following the six steps for thematic analysis.

RESULTS

Results for the quantitative data

Socio-demographic characteristics of the study participants

More than half (55.4%) were female, and the median age (interquartile range) was 27 (23, 36) years. Almost all (94.4%) were literate and had completed secondary education (Table I).

Table I: Frequency distribution of participants according to socio-demographic characteristics (n=216)

Characteristic	Categories	Frequency n(%)
Facility	Facility 1	65(30.1)
	Facility 2	151(69.9)
Sex	Female	119(55.1)
	Male	97(44.9)
Age category (in Years)	18-29	124(57.4)
	30-35	72(33.3)
	36-65	20(9.6)
Highest level of Education	None	4(1.9)
	Primary	8(3.7)
	Secondary	62(28.7)
	Tertiary	142(65.7)
Ability to read and write	Yes	211(97.7)
Marital Status	Single	134(62.0)
	Married	75(34.7)
	Widowed/Separated/Divorced	7(3.3)
Religion	Catholic	76(35.2)
	Protestant	67(31.0)
	Muslim	26(12.0)
	Other	47(21.8)
Occupation	Unemployed	12(5.6)
	Studying	86(39.8)
	Business/self-employed	59(27.3)
	Civil/ public service /formal employment	48(22.2)
	Farming or other	11(5.1)
Given an opportunity to ask questions	Yes	186(86.1)
	No	30(13.9)

n-number, %-percentage

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Service-related factors

More than three-quarters (>83.0%) of the patients needed a crown, and this was their first time to have such treatment. Majority (85.2%) noted that information had been provided by the dentist who would be treating, while for the rest it was from another dentist in the same practice. Almost all (96.3%) patients reported to have received the information at a prior appointment or before the start of the procedure, while for 3.7% of them, information was provided as the procedure was being conducted. All patients reported having received information in an verbal discussion, and videos or dental models were utilised among 4.6 % and 9.3% of them, respectively.

Information provided and assessment of patient's subjective (perceived) understanding of information provided

Almost half (48.4%) reported that they had not received information about risks. More than two-thirds reported to have understood either well or very well the information regarding their dental problem, the proposed treatment procedure, and its benefits, whereas less than a third (31.4%) felt they understood information regarding the possible risks. Notably, about 15 to 20% of them felt they did not understand or somewhat understood the information provided regarding procedures, alternative treatment, or risks (Table II).

Objective understanding of the information provided

Overall, approximately 13.4% of the participants had an adequate objective understanding of the information provided regarding FPT (Table III). Most items assessing participants' understanding of treatment procedures (P1, P2, P3, P4) were answered correctly, with more than two-thirds (68.1%) having an adequate understanding. Conversely, less than one-third of the participants had an adequate understanding of the risks, alternative treatment options, and benefits,

Table II: Frequency distribution of participants according to the subjective (perceived) understanding of the information provided (n=216)

Characteristic	Not informed	I didn't understand this at all	Somewhat	Well	I understood this very well
The problem/diagnosis	2(0.9)	2(0.9)	19(8.8)	96(44.4)	97(44.91)
The treatment/procedures you will undergo	24(11.1)	7(3.2)	34(15.8)	80(37.0)	71(32.9)
The alternative treatment(s) to the chosen option	48(22.2)	6(2.8)	27(12.5)	68(31.5)	67(31.0)
The benefits of the treatment	7(3.3)	2(0.9)	22(10.2)	88(40.7)	97(44.9)
The risks of undertaking the treatment	104(48.2)	14(6.5)	28(12.9)	41(19.0)	29(13.4)
Overall, how well did you understand the information provided?	2(0.9)	1(0.5)	27(12.5)	101(46.8)	85(39.3)

Table III: Frequency distribution of participants' responses according to objective assessment of understanding (n=216)

Domain	Item	Participant responses			Understanding		
		Agree	Unsure	Disagree	Adequate†	Moderate†	Inadequate†
		n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Treatment procedures	**P1**: The dentist will numb my teeth and gums on the affected side by giving medicine in an injection in my mouth	182(84.6)*	30(14.0)	3(1.4)	147(68.1)	66(30.5)	3(1.4)
	P2: Part of the tooth and or filling will be cut to prepare for the crown/ bridge	154(71.6)*	56(26.1)	5(2.3)			
	P3: They will use some material to take measurements/ impressions of the teeth and mouth	158(73.5)*	54(25.1)	3(1.4)			
	P4: The treatment may take 2 or more appointments to be completed	168(78.2)*	42(19.5)	5(2.3)			
	P5: The crown or bridge can easily be removed in case there is a need for adjustment.	106(49.3)	76(35.4)	33(15.3)*			

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Benefits of the treatment	**B1:** The prosthesis will improve my appearance or speech	159(74.0)*	47(21.9)	9(4.2)	67(31.0)	142(65.7)	7(3.3)
	B2: The crown/bridge will improve my chewing ability	175(81.4)*	38(17.7)	2(0.9)			
	B3: The crown or bridge will function as comfortably as your tooth	163(75.8)*	38(17.7)	14(6.5)			
	B4: The crown/bridge will be fixed onto your teeth/tooth; you will not need to remove it from time to time	125(58.1)*	57(26.5)	33(15.4)			
	B5: This treatment is permanent, and I don't need any home care.	105(48.8)	81(37.7)	29(13.5)*			
	B6: The artificial tooth is quite tough and may be used to open packaging, open bottles, or crack hard foods.	49(22.8)	64(29.8)	102(47.4) *			
Probable risks	**R1:** You may experience slight pain or sensitivity in the prepared tooth/teeth if they are not root canal treated.	126(58.6)*	82(38.1)	7(3.3)	51(23.6)	139(64.4)	26(12.0)
	R2: The dental crown or bridge may chip or fracture.	89(41.4)*	104(48.4)	22(10.2)			
	R3: The underlying tooth/ teeth may require root canal treatment before or after the procedure.	136(63.3) *	69(32.1)	10(4.7)			
	R4: The underlying tooth may develop tooth decay.	62(28.8) *	119(55.4)	34(15.8)			
	R5: Over time, the gums around the crowned tooth / teeth may shift, exposing the margins	43(20.0)*	141(65.6)	31(14.4)			
	R6: Sometimes the crown may become loose over time	76(35.4) *	109(50.7)	30(13.9)			
Alternative treatment options	**A1:** Having this treatment is the only option for managing this problem	93(43.3)	48(22.3)	74(34.4)*	58(26.9)	103(47.7)	55(25.4)
	A2: Can replace the tooth or teeth with a removable option/ denture	117(54.4)*	70(32.6)	28(13.0)			
Overall objective understanding	29(13.4)	185(85.7)	2(0.9)				

*Denotes the correct response, †Adequate, moderate, and inadequate levels of understanding were considered if the participant had correctly answered and obtained ≥80%, 79 to 50%, and <50% of the maximum possible score for a specific domain of information.

23.6%, 26.8%, and 31.0%, respectively (Table III).

Association of subjective and objective understanding of information among participants

There was no significant association between the different levels of subjective understanding and overall objective understanding among the participants (P=0.064, χ^2 test).

Qualitative Results

The participants had a mean age (SD) of 30.3(11.9) years. Most (17/19) participants had attained formal education up to secondary school. Six had formal jobs or personal businesses, two were farmers, and 11 were students (nine pursuing a diploma or bachelor's degree, one a postgraduate degree, and one secondary school education).

Three key themes emerged from the qualitative data: 1) patients' perceptions of the information received, 2) patient awareness of the treatments, and 3) suggestions on how to improve patients' understanding of information.

Theme 1: Patient perceptions of the information received

The majority (n=16, 84%) of the participants reported that they felt they had received adequate information about their management to make informed decisions. However, two university students felt that they needed more information and searched on the internet, as one participant stated:

> *'Yes, I did. I went back and saw some videos [..]. I did some search and I went to Google, I read about it. I saw the different types [fixed prostheses]; I saw the metallic and their disadvantages.' (IDI 7)*

However, on exploring the information received for each specific domain, less than half (n=9, 47.4%) indicated that they had no recollection of being told about the details of the procedures or possible risks. A few participants (n=3, 15.7%) reported knowing only one benefit of the treatment, which

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directly resolved their chief complaints. For instance, patients who wanted to restore or replace a missing anterior tooth to enhance their appearance claimed that the only benefits of the bridge or crown they knew of were to improve their esthetics.

Participants felt that the main importance of the information provided was to educate and guide them to make informed treatment decisions about their treatment, as well as to allay their worries arising from certain misconceptions, as expressed by the quotes.

'It [information] is important because it helps to make a rational decision […]. People fear these procedures. They say, how do you go for a root canal treatment? It is very risky, a challenge can come, and you can get an accident […], so when you are given all the information, it helps you make a rational decision.' (IDI 7)

'It is important because first of all I make a choice that is informed, that suits me because the dentist might do something that is general, but I have my [personal] fears, so if I am given a variety of options, I go with something that I am comfortable with and that suits me'. (IDI 17)

Theme 2: Participants' awareness about the fixed prosthodontic treatment they were to undergo.

Most participants (n=13, 68.4 %) indicated that the information provided was easy to understand according to them. However, some participants reported that they did not understand some of the information and had to trust the dentist to make correct decisions. A female with a tertiary education level indicated that she could not understand the information but trusted the dentist to do the right thing.

Information that was difficult to understand included treatment procedures and alternative treatments, especially when technical terms were used in the discussion, as expressed in the participant quote below.

'The treatment type and procedure need to be explained in detail because some of the medical terms are not friendly […]. The other two treatments were not clear because they told me three treatments, but I didn't understand well the other two'. (IDI 14)

Overall, the majority (n=16, 84%) described explicitly their problem and knew at least one reason for the treatment and benefits of the FPT. Only one participant was aware of two or more of the possible risks. Several participants had no information on the details of the procedure or risks.

'No, I am not sure of what exactly will be done. I am neither sure of what I will go through nor the number of appointments'. (IDI- 1)

It is worth noting that one participant did not know the reason for the treatment they had agreed to undergo.

'I don't even know the reason why I need a crown. I haven't got the information why they are putting a crown […]. Although I agreed, but I don't know why the tooth needs a crown'. (IDI 8)

Theme 3: Suggestions for improving communication and patients' understanding

More than a third (n=7, 37%) suggested that the use of visual aids may improve patients' understanding of the information. Visual aids such as videos, pictures, or models should be used during discussions or shared on social media to improve the patients' understanding. Other suggestions included the use of simplified language during the discussion, allowing the patient sufficient time to make decisions that may involve another appointment, providing information at several appointments, encouraging patients to ask questions, using local languages, and providing a more detailed explanation of the treatments.

'I think in clinics, having visual aids will be one of the easiest ways to communicate to patients. For the pamphlets, people don't read them'. (IDI 17)

'I think in this era of communication, online and social media are the best ways of communication. With a particular patient, you can share pictures, for example, Dr. X shared with me. Or send a link of a procedure, and the person sees what is going to happen to them. Well, if they haven't understood the verbal information, they can see the video of the process, so that they know how it's going to be'. (IDI 7)

'Maybe by simplifying some of the terms and the language used. Simplify the way they communicate to make it understandable to everyone'. (IDI 9)

DISCUSSION

The study findings indicated that the majority of patients did not have an adequate understanding of the FPT they were to undergo on the objective assessment. These findings are consistent with those from several studies conducted in clinical settings, which showed that most patients did not have an adequate understanding of information.[5, 15-17] For example, a systematic review of articles on understanding informed consent for surgery found that 6 out of the 21 (29%) studies reported that participants had inadequate understanding of the information provided during the consent process.[15] In contrast, Sahai et al reported that most (> 90%) of participants had an adequate understanding of the information provided in a leaflet or video before laparoscopic surgery in the United Kingdom.[18] The difference in results may stem from the present study used mainly verbal discussions to convey information for a complex treatment, fixed prosthodontic treatment, and the variability of the information provided by the different dentists, while Sahai et al utilised other methods like information leaflets, consent forms, and videos to deliver information.[18]

The study's findings, that few participants had an adequate understanding, raise various concerns; about the effectiveness of methods used for communication of treatment information, whether patients in the present study were in a position to make informed decisions, and provide valid informed consent, as the four criteria of information disclosure, competence, understanding, and voluntariness must be met. As suggested by several authors, it is proposed to incorporate the use of adjunct educational materials, either delivered in written form or visual tools, for improvements in patients' understanding of consent information and the delivery of standardised information.[5, 10]

Furthermore, the qualitative results revealed that difficulties in understanding information were partly due to the use of medical terms. Goltileb et al observed similar findings and noted that the use of medical phrases during doctor-patient discussions may lead to confusion among patients.[25] Thus, it is proposed that simplified language should be used during

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the consent process, as well as adding communication courses to dentists' training to promote the development of requisite knowledge, skills, and expertise.[22, 27, 28]

In addition, several participants in both study arms noted that they had not received any information about the risks or treatment procedures. The results are comparable to findings by Brezis et al., who observed that half and two-thirds of the patients who underwent invasive procedures did not recall receiving explanations about risks or alternative treatment options, respectively.[29] Despite these findings, various ethical codes, including the local guidelines of Uganda, stipulate that dentists must provide patients with adequate and balanced information, including probable risks, to enable patients to make informed decisions regarding the proposed treatment.[4, 8, 9] In addition, most procedures are complicated, and the attendant risks or benefits are unknown to patients.[21] Thus, dentists are required to disclose to patients the material risks associated with the proposed procedures, defined as those risks that are most relevant to the patient, that are the most common, and the most serious.[4] Without providing such information, a dentist breaches their duty, resulting in potential negligence.[1]

Furthermore, the study findings revealed no significant association between subjective and objective understanding, which may imply that participants who thought they had understood the information actually did not. This discrepancy between patients' subjective perception of understanding and their actual comprehension indicates possible biases in self-reports by patients and the need to provide comprehensive treatment information. This also indicates a challenge to practitioners, as they may proceed with treatment on the assumption that whenever patients answer affirmatively to a general question on whether they have understood such information, then they have indeed understood. Since obtaining valid informed consent is a stringent moral and legal obligation of practitioners, and the burden of proof of understanding usually lies on practitioners,[4] there is a need to close this gap. It is necessary to devise strategies to enhance the delivery of information and patient understanding and develop metrics for assessing patient understanding, such as asking questions at the end of the informed consent process, as suggested by study participants.

The findings revealed that the overall objective understanding of information was as low as 13% in a predominantly literate study sample. Thus, it could be worse among semi-literate and illiterate patients as several studies have noted that information recall and patient understanding are affected by literacy level.[28, 30] This emphasizes the critical need for future research to diverse interventions for communicating complex information, such as the use of visual aids, leaflets, and measures for communicating complex concepts in digestible chunks[22-24] to improve patients' understanding of the information provided during the informed consent process for dental care. In addition, there is a need to develop innovative methods for objective assessment.

Limitations of the study include: 1) the study findings may not be generalized to all patients in Uganda as participants were recruited from two dental facilities in urban area, and 2) the lack of documentation concerning what was discussed during the informed consent process for the participants and relying on patients' recall as a reporting tool could have influenced the responses with recall bias. (3) There may have been variability in the information provided during the consent process.

CONCLUSION

Most patients who received FPT at the two dental care facilities did not adequately understand the treatment they were to undertake. Based on the data, it is suggested to devise measures for the objective assessment of patient understanding before obtaining consent or starting treatment. In addition, to develop interventions such as visual tools or consent forms to improve patient understanding of information deemed difficult to understand. To improve the generalizability of study findings, similar studies should be conducted with larger sample sizes and across multiple regions, including rural and urban areas.

Conflicts of interest

The authors have no conflicts of interest to declare.

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